SECTION VIII

MEDICAL DEVICE REPORTS (MDRs)

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MEDICAL DEVICE REPORTS/VIGILANCE REPORTS

METAL/METAL SEMI-CONSTRAINED TOTAL HIP PROSTHESES

Inclusive dates: January 1, 1992 to June 29, 2000.

A reasonable effort was made to find all adverse reports made for these devices under the Medical Device Reporting (MDR) regulations and under the vigilance reporting requirements for medical devices under Article 10 of the European Medical Devices Directive (MDD). A search of the publicly available information yielded one report filed for metal/metal semi-constrained total hip prostheses. However, it is possible that a small number of additional reports could have been made using improper product codes, erroneous device descriptions, etc. In addition, the FDA may have access to additional reports made after June 29, 2000.

A review of the published literature was performed to provide a summary of the device related adverse events reported for metal/metal hip prostheses.

A. MDR/Vigilance Reports

A summary of the one MDR report obtained for a metal/metal hip prosthesis is provided below. There were no vigilance reports obtained from searches conducted of the databases available for the member states comprising the European Economic Community (EEC).

Manufacturer:	Sulzer Orthopaedics, Inc. 9900 Spectrum Austin, TX 78717
Device Description:	Acetabular Insert 28x55 Metasul APR
MDR Report Key:	29355620-2000-00012
Product Code:	KWA
Report Date:	4/24/2000
Catalog No.:	4340-28-055
Device Lot No.:	1251199
Event Description:	Allegedly the anti-rotation pin became dislodged from the polyethylene acetabular insert.
Patient Outcome:	Hospitalization.

B. Summary of Published Adverse Events

A survey of the published literature resulted in the following adverse events reported for these devices.

1. Wagner, Michael and Heinz Wagner. "Preliminary Results of Uncemented Metal on Metal Stemmed and Resurfacing Hip Replacement Arthroplasty."; Clin. Orthop., No. 329S (1996): S78-S88.

   This article reports on a series of 70 patients in Europe with metal/metal semi-constrained total hips implanted during 1990-1992. There was one early dislocation with the patient refusing further treatment; one late infection requiring removal of the prosthetic implant components. Periarticular calcification in two patients requiring reoperations was also reported.

2. Dorr, L. D., K. R. Hilton, Z. Wan, G.D. Markovich, and R. Bloebaum, Ph.D. " Modern Metal on Metal Articulation for Total Hip Replacments."; Clin. Orthop., No. 333 (1996): 108-117.

   This article reports on a series of 54 patients treated in the U.S. with metal on metal semi-constrained total hips from 1991-1994. There was one infection and two dislocations; one of these dislocations required revision of the prosthesis three years postoperatively.

3. Weber, B.G. " Experience With the Metasul Total Hip Bearing System."; Clin. Orthop., No. 329S (1996): S69-S77.

   This article reports on a series of 110 patients treated in Europe with metal on metal semi-constrained total hips from 1988-1992. There were five early failures attributed to loosening reported. There were two additional complications of trochanteric bursitis (one case) and painful ectopic ossification (one case), neither case required reoperation.

4. Hilton, K.R., L.D. Dorr, Z. Wan and E.J. McPherson. " Contemporary Total Hip Replacement With Metal on Metal Articulation."; Clin. Orthop. No. 329S (1996): S99-S105.

   This article updates a previous report by Dorr, et al. (See ref. 2) There was one additional dislocation reported for this series.

5. Doorn, P.F., J.M. Mirra, P.A. Campell, and H.C. Amstutz. "Tissue Reaction to Metal on Metal Total Hip Prostheses."; Clin. Orthop. No. 329S (1996): S187-S205.

   Nine metal/metal hip implants retrieved from nine patients underwent histological evaluation to study the tissue reaction around the prostheses. Four McKee-Farrar, one APR and one Apollo metal/metal total hip prostheses and three McMinn metal/metal total surface replacement hip prostheses were evaluated. The duration of implantation ranged between seven months and 25 years. Implants were retrieved due

to aseptic loosening (4), pain (2), dislocation (1), femoral fracture (1) and death (1). While many of the common tissue responses to metal/polyethylene articulations were also noted for the metal/metal devices, however, overall these reactions appeared less intense.

6. Iida, H., E. Kaneda, H. Takada, K. Uchida, K. Kawanabe, and T. Nakamura. "Metallosis Due to Impingement Between the Socket and the Femoral Neck in a Metal-on-Metal Bearing Total Hip Prosthesis: A Case Report."; J Bone Joint Surg. Vol. 81(A) (1999): 400-3.

   This article reports on a single patient who suffered a failure of her metal-on-metal hip prosthesis 12 months following her surgery. The patient had no prior history of dislocation or other major complication. The prosthesis was shown to be loose on x-rays at 12 months and osteolysis was suspected in the calcar and trochanter regions of the femur. Examination of the retrieved titanium alloy femoral prosthesis and the cobalt-chrome alloy acetabular prostheses revealed markings consistent with impingement between the socket and the femoral neck during maximum hip flexion. Histological examination of the psuedocapsular tissue revealed particles of titanium, but cobalt and chromium were not detected. The authors concluded that the source of the metal debris was from the femoral prosthesis. The authors further concluded that this type of complication can occur anytime, without symptoms or associated complications and questioned the use of titanium in the manufacture of this implant.

7. Campell, P., H. McKellop, R. Alim, J. Mirra, S. Nutt, L. Dorr, and H.C. Amstutz. "Metal-On-Metal Hip Replacements: Wear Performance and Cellular Response to Wear Particles." In Cobalt-Based Alloys for Biomedical Applications. ASTM STP 1365., editors J.A. Disegi, R.L. Kennedy and R. Pilliar, 193-209. West Conshohocken, PA: ASTM publishers.

   This article reports on 20 second generation metal-on-metal hip prostheses retrieved from patients after use ranging from nine months to 6.5 years. The specific aims of this study of retrieved devices were to examine the amount of wear, study the histological appearance of the periprosthetic tissues and characterize the wear particles generated *in vivo*. There were 10 total hip and 10 surface replacement hip prostheses configurations available for evaluation. Implants were made available due to a variety of reasons including loosening, debonding, component breakage, infection and death.

   Eighteen of the 20 retrieved prostheses had at least one component measured for wear. For those components in which wear could be measured, the amount of wear ranged from 3-32 microns. Two of the total hip prostheses exhibited clusters of micropits in the main bearing area, but these did not appear to be associated with high wear.

   Histological evaluation revealed metallosis occurred in five cases. Impingement of the titanium alloy femoral components with the acetabular shell, debonding of the

porous coating and breakage of the femoral component were cited as the likely causes in four of these cases. For the fifth case, discoloration was likely due to cobalt-chrome particles released during the wear-in phase of the components. The histology for another case revised due to distal femoral osteolysis, was inconsistent with wear-induced osteolysis. Extensive necrosis was noted for two other cases, but no clear association between necrosis and metal wear particles could be made. Except for the five metallosis cases, there were fewer macrophages and wear particles than is typically seen in tissues around metal-polyethylene hip prostheses. Two consistent forms of cobalt-chrome particles were noted. One was a dense elongated form that commonly had a defined edge. The second, and the most common, form had less defined edges with a non-homogeneous, amorphous texture. Particle size was comparable between the total hip and surface replacement hip prostheses.

Conclusions are summarized as follows: 1) wear of the metal-on-metal articulations was substantially lower than for metal-polyethylene articulations, 2) third body damage was noted in varying degrees on all components, 3) histology and particle morphology were consistent with the low wear of these bearings, 4) cellular reaction to the metal particles could be described as mild, and 5) further histopathological studies and measurements of *in vivo* wear of metal-on-metal total hip replacements are recommended.

8. Albrecht-Olsen, P, Owen-Falkenberg, T, Burgaard, P, Andersen, PB. Nine-Year Follow-up of the Cementless Ring Hip. *Acta Orthop Scand*, 60:1:77-80, 1989.

   Albrecht-Olsen et al. reviewed 238 Ring prostheses implanted during the period 1968-1979. Of those cases, 127 with a median follow-up of 9 years were available for evaluation with 90% of those patients demonstrating excellent/good results upon self assessment. Using the Charnley scale, 87% had a pain score of 4 or greater (score of 6 = no pain), 76% had a motion score of 4 or greater, and 57% had a walking score of 4 or greater. The author cites an infection rate of 2.5% (6 deep infections, 16 superficial infections). Four dislocations were also encountered. At the time of this evaluation, 17% (n=40) of the patients had been revised, mainly due to pain. Overall results predicted an 81% survival rate at 12 years, comparable to outcomes seen with metal-on-polyethylene articulation

9. Almby, B, Hierton, T. Total Hip Replacement: A Ten-Year Follow-up of an Early Series. *Acta Orthop. Scand.*, 53:397-406, 1982.

   Almby reported on 93 patients receiving the Muller device, 57% of which had been followed for more than 10 years. Using the Charnley scale (6 possible points in each category), 90% had pain rating of 4 or better or a range of motion greater than 100°. Nine deep infections were reported. Thirty patients died (26 unrelated to device, 1 embolus, 1 ileus, 1 renal failure, 1 septic). Twenty-nine patients were revised (19 aseptically loose, 7 septically loose, 4 stem fractures, 1 fracture). Twenty-three acetabular and 16 femoral components showed signs of loosening. Femoral loosening was secondary to calcar resorption and cement settling in most

cases. Survivorship in this series was calculated to be approximately 80% at 5 years and 57% at 10 years.

10. Andrew, T.A., Berridge, D, Thomas, A, Duke, RNF. Long-term Review of Ring Total Hip Arthroplasty. *Clinical Orthopedics and Related Research,* 201:111-122, 1980.

    Andrew presented his results of 116 Ring patients followed for 8 years. Using the Harris scoring system (100 points possible), 33% of the patients had 80 points or greater with another 13% exhibiting total scores of 70-80. Using the Ring evaluation, 49% of the patients rated excellent or good. Two deep infections and 4 dislocations were encountered. Other complications included grade IV heterotopic ossification (5), fracture (4), embolic event (7), and sciatic palsy (1).

11. Djerf, K, Wahlstrom, O. Total Hip Replacement Comparison Between the McKee-Farrar and Charnley Prostheses in a 5-Year Follow-up Study. *Acta Orthop. Scand.*, 105:158-162, 1986.

    Djerf presents results on 107 McKee-Farrar and 70 Charnley devices with 5 years followup. Analysis revealed 94% of patients to have no pain and 78% to have improved flexion. Unrelated death occurred in 12% of the patients. Six infections (3.4%) and 4 dislocations (2.3%) were reported. Other complications included trochanteric problems (2.8%), nerve injury (1.7%), deep venous thrombosis (1.7%), pulmonary embolus (0.6%), fracture (0.6%), and ossification (0.6%). Loosening was evident in 32% of the cases. Analyses showed no significant difference in the outcomes of either implant.

12. August, AC, Aldam, CH, Pynsent, PB. The McKee-Farrar Hip Arthroplasty: A Long Term Study. *Journal of Bone and Joint Surgery*, 68B:4:520-527, Aug. 1986.

    Results of 175 patients with the McKee-Farrar device at an average 13.9 years of follow-up are presented by August. Using the Harris evaluation, the average total score was 76.4, with 48.9% having excellent/good outcomes. On self assessment, 90% of the patients rated themselves as having a satisfactory outcome. Sixty-four patients were revised, mainly for loosening, stem fracture and bone fracture. Over 50% of the stems and cups showed signs of looseness radiographically. Additionally, the cup showed signs of protrusion in 62.5% of rheumatoid patients. Heterotopic ossification (grade IV) was reported in 2.7% of the cases. August calculated survival at 84.3% at 14 years and 27.5% at 20 years.

13. Jantsch, S, Schwagerl, W, Zenz, P, Semlitsch, M, Fertschak, W. Long-term Results After Implantation of McKee-Farrar Total Hip Prostheses. *Acta Orthop. Scand.*, 110:230-237, 1991.

Jantsch analyzed followup at 14 years in a series of 248 patients with 330 McKee-Farrar devices. Only 56% of the patients were followed clinically to this period (24% died, 17% untraceable, 3% refused participation). Using the Mayo rating system, 48% of the patients were found to have excellent/good ratings (62% if revisions are excluded). Based on radiographs available, 34% of the cups and 26% of the stems were unstable. There were 36 retrievals (22 cup and stem, 7 cup, 7 stem).

14. McKee, GK, Chen, SC. The Statistics of the McKee-Farrar Method of Total Hip Replacement. *Clinical Orthopedics and Related Research*, 95:26-33, Sept. 1973.

    McKee reports on four series of patients treated with the various iterations of the McKee-Farrar device from 1956-1971. As shown in the attached tables, postoperative outcome improved through each design iteration, with approximately 89% achieving excellent or good outcomes in the 1965-69 series (4-7 year followup) and 97% achieving excellent or good outcomes in the 1971 series (2 year or less followup). Retrievals have occurred in 4% of the 1965-69 series and 0% of the 1971 series. Fifteen (15) deaths were reported in the 1965-69 series; two were reported in the 1971 series. The reported rate of infection was 4% in the 1965 series and 0% in the 1971 series. Two dislocations (2%) were also reported in each of these series. Other complications include pulmonary embolus, deep venous thrombosis, shaft perforation, hematoma and heterotopic ossification.

15. Ring, P. Press-Fit Prostheses: Clinical Experience. *Osteoarthritis in the Young Adult Hip: Options for Surgical Management.* Pp. 220-232, edited by D Reynolds and M Freeman, Churchill Livingstone Publishing, 1989.

    Ring presents results on 106 metal-metal Ring prostheses with 7-17 years followup. Postoperatively, 83% were assessed as excellent/good clinically. Outcomes of the various design iterations is again presented in this article. Thirteen retrievals have occurred (7 femoral failures, 2 pelvic failures, 3 combination failures, 1 ankylosis). Survivorship of patients implanted from 1968-73 was 81% at 18 years; survivorship was 95% at 16 years for those implanted from 1972-79.

16. Schmalzried, TP, Szuszczewicz, ES, Akizuki, KH, Petersen, TD, Amstutz, HC. Factors Correlating with Long Term Survival of McKee-Farrar Total Hip Prostheses. *Clinical Orthopedics and Related Research*, 329S:48-59, Aug. 1996.

    Thirteen McKee-Farrar patients (15 devices) with an average follow-up of 23.7 years are presented by Schmalzried. The average Harris hip score of these patients was 86 with 11 patients having an excellent/good rating. These patients outscored a matched metal-on-poly control population on the SF36 Health Status questionnaire. Activity levels were also reported to exceed the averages for this age population. The only complication reported is that of lysis in three femurs and one acetabulum.

17. Zaoussis, AL, Patikas, AF. Experience with Total Hip Arthroplasty in Greece, the First 20 Years: A Particular Reference to Long-Term Results with the McKee-Farrar Technique. *Clinical Orthopedics and Related Research,* 246:39-47, Sept. 1989.

Zaoussis presents results on 38 McKee Farrar patients followed for 12-20 years, with 26 having greater than 15 years followup. At the time of this evaluation, 45% were found to have very good outcomes. Fifty-three percent (53%) of the patients were pain free and 79% had 60-90° range of motion. Three infected components and four loose components were retrieved. There have been five dislocations (all in one patient). Nine components show looseness. Other complications include five peroneal nerve palsies, one cortical perforation and one ossification.